

REMARKS

Claims 1, 23, 33-36, 85, 92, and 97-100 have been amended solely for greater clarity. The claim amendments are fully supported by the specification. No new matter has been introduced and no new issue has been raised. These amendments have been made solely to expedite prosecution of the application. Applicants reserve the right to pursue claims of similar or differing scope in the future.

Applicants note that the Examiner has withdrawn the objection to drawings and the objection to claims 23, 28-36, 85, 88-89 and 92-94.

Applicants respectfully request reconsideration in view of the following remarks. Issues raised by the Examiner will be addressed below in the order they appear in the Office Action.

Claim Rejections under 35 U.S.C. § 112, 2<sup>nd</sup> Paragraph

Claims 1, 23, 33-36, 85, 92 and 97-100, and therefore dependent claims 2-6, 24, 26-32, 37, 73-74, 86-91, 93-96 & 101-104, are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention.

First, the Examiner asserts that it is not clear whether Applicants "intend to encompass only those primer and/or collar sequences which anneal to a complementary nucleic acid under stringent polymerase reaction conditions or within a particular temperature range or salt concentration," or "intend a much broader interpretation, including nucleic acid sequences which may only anneal to one or two bases – even within a polymerase reaction." Office Action, the paragraph bridging pages 3 and 4.

Solely to expedite prosecution of the application, Applicants have amended claims 1, 23, 33-36, 85, and 92 to recite "anneals specifically" in place of "are capable of annealing," "is capable of annealing," or "being capable of annealing," thereby rendering the rejection moot. Support for this can be found at page 6, lines 18-19, of the application. One of skill in the art understands that "specifically" means that there is correct base pairing.

Second, the Examiner asserts that there is insufficient antecedent basis for the limitation "said polymerase" in claims 97-100. Office Action, page 4, lines 3-5.

Applicants respectfully disagree. One of skill in the art would know that a polymerase is present in a polymerase reaction. Nevertheless, solely to expedite prosecution of the application, Applicants have amended claims 97-100 to specify that said polymerase reaction is mediated by a DNA polymerase or a reverse transcriptase.

In view of the above, Applicants submit that all claims are clear and definite to one of skill in the art. The Examiner is respectfully requested to reconsider and withdraw all rejections under 35 U.S.C. § 112, second paragraph.

Claim Rejections under 35 U.S.C. § 112, First Paragraph

Claims 1-6, 23-24, 26-37, 73-74 and 85-104 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Applicants respectfully traverse this rejection.

Specifically, the Examiner asserts that the claimed subject matter is directed to a genus which comprises "ANY primer or ANY collar sequence which can anneal during a polymerase reaction to ANY portion (however long or short) of any polypeptide-encoding portion of a nucleic acid. Limitation of such sequences to those which are 10 or 15 nucleotides in length and/or to those capable of annealing 'during a polymerase reaction' does not render the genus significantly narrower as any portion of the sequence must, as before, simply be capable of annealing to ANY portion of any polypeptide-encoding portion of any nucleic acid as long as the polypeptide-encoding portions to which the primer anneals are at least 20 nucleotides apart."

Office Action, page 7, lines 8-19.

It appears that the Examiner has broadly interpreted the claims because of the alleged indefinite recitation of "capable of annealing." As described above, Applicants have amended independent claims to recite "anneals specifically" in place of "are capable of annealing," "is capable of annealing," or "being capable of annealing" solely to expedite prosecution. Applicants submit that the claimed subject matter as amended is described sufficiently in the specification to indicate that Applicants were in possession of the invention at the time of filing.

Applicants submit that the final guidelines for 35 U.S.C. § 112 clearly state that there is a *strong presumption* that the specification as filed provides adequate written description support

for the claimed invention. MPEP 2163.03 also states that “rejection of an original claim for lack of written description should be rare.” A disclosure as filed is *prima facie* adequate.

Also pursuant to MPEP 2163.02: “An objective standard for determining compliance with the written description requirement is, ‘does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed.’… Whenever the issue arises, the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed.... An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention.... Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was ‘ready for patenting’ such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete.”

In view of the guidelines recited above and the reasoned proffered below, Applicants respectfully submit that the written description requirement is met for the claimed invention.

Generally, there is an inverse correlation between the level of skill and knowledge in the art and the specificity of disclosure necessary to satisfy the written description requirement.  
Information which is well known in the art need not be described in detail in the specification.  
See, e.g., *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1379-80, 231 USPQ 81, 90 (Fed. Cir. 1986).” (emphasis added, see MPEP 2163, Section II(A)(2)).

Applicants submit that the level of skill and knowledge in the art regarding construction of plasmids directed to a target nucleic acid is very high, thus there is no need to describe in detail in the specification various target nucleic acid sequences, related primer sequences and collar sequences which anneal to the target nucleic acid sequences, or portions of the target nucleic acid sequences which anneal to the primer sequences. The specification provides specific examples of the primer sequence and the collar sequence, such as SEQ ID NOs: 3-4 which anneal to a portion of the kappa light chain and SEQ ID NOs: 7-8 which anneal to a portion of the heavy CH1 constant region (see, e.g., Example 1 on pages 17-19), which are

representative species of the claimed genus. A skilled artisan can readily envision other primer sequences and collar sequences which anneal to desired target nucleic acid sequences.

In summary, the instant specification provides adequate written description for the claimed subject matter, and all pending claims satisfy the written description requirement of 35 U.S.C. § 112, first paragraph. Reconsideration and withdrawal of the rejections are respectfully requested.

**Claim Rejections under 35 U.S.C. § 112, First Paragraph**

Claims 1-6, 23-24, 26-32, 73-74 and 85-104 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The Examiner asserts that this is a new matter rejection.

Specifically, the Examiner asserts that "[t]he specification as originally filed does not provide support for the invention as now claimed: 'a primer sequence of at least 10 nucleotides' or 'a collar sequence of at least 10 nucleotides' (claims 1-6, 23-24, 26-32, 73-74 and 85-100) or 'a primer sequence of at least 15 nucleotides' or 'a collar sequence at least 15 nucleotide' (claims 101-104). The specification does not provide sufficient blazemarks nor direction for the instant primer/collar sequence lengths encompassed by the above-mentioned limitation, as currently recited." Office Action, page 9, lines 8-17.

Applicants respectfully disagree. The specification provides sufficient description of the claimed plasmid, including the lengths of primer sequences and collar sequences. For example, the specification describes that “[t]he downstream primer and upstream collar sequence should be of sufficient length to support specific and stable hybridization to the target complementary mRNA. The annealing sequences may individually contain from about 10 nucleotides to about 50 or more nucleotides in length. Preferably, the individual annealing sequences are 15 to 35 nucleotides in length” (see e.g., page 6, lines 18-22, emphasis added). In addition, the specification provides examples of the portions of encoding mRNAs to which the primer sequence and the collar sequence anneal (see, e.g., Table 1 on page 9). Further, the specification provides specific examples of the primer sequence and the collar sequence, such as SEQ ID NOs: 3-4 and 7-8 (see, e.g., Example 1 on pages 17-19).

In view of the teachings of the specification and the knowledge in the art, one of skill in the art would appreciate that the specification provides sufficient description and guidance for the primer/collar sequence lengths recited in the pending claims. Accordingly, all pending claims satisfy the written description requirement of 35 U.S.C. § 112, first paragraph. Reconsideration and withdrawal of the rejections are respectfully requested.

Claim Rejections under 35 U.S.C. § 102(b)

Claims 1-6, 23-24, 26-32, 37, 73-74, 97-98 and 101-102 are rejected under 35 U.S.C. § 102(b) as being anticipated by Young et al. (P.N.A.S., 80:1194-1198, 1983; of record). Applicants respectfully traverse these rejections.

Specifically, the Examiner asserts that "the claims do NOT require that the first portion and the second portion of the polypeptide-encoding nucleic acid be separated by at least 20 nucleotides; the claims require only that the primer and collar sequences, each of at least 10 nucleotides in length, be capable of annealing to portions of a first and second portion of a polypeptide-encoding portion of a nucleic acid which are separated by 20 nucleotides." Office Action, the paragraph bridging pages 11 and 12.

Applicants have amended claim 1 to state that the first and second portions of the nucleic acid are separated by at least 20 nucleotides and further that the at least 20 nucleotides do not specifically bind to either the primer or collar sequences. It is urged that this language makes it very clear that claim 1 and its dependent claims does require that the first portion and the second portion of the polypeptide-encoding nucleic acid are separated by at least 20 nucleotides.

In view of the above, the plasmid of claim 1 features that the first portion and the second portion of the polypeptide encoding portion of the nucleic acid are separated by at least 20 nucleotides. By contrast, Young et al. fail to teach or suggest this feature - there is simply no gap or separation between the "first portion" and the "second portion" of Young et al. Accordingly, Young et al. fail to anticipate independent claim 1. For the same reasons, Applicants submit that all claims depending from claim 1 are not anticipated by Young et al.

Further, Applicants point out that Young et al. fail to anticipate independent claims 23, 85, and 92. Applicants submit that the term "portion" in the amended claims is clearly defined

to be a portion of a nucleic acid encoding an antibody, the framework region associated with an antibody or the constant region associated with an antibody. By contrast, Young et al. simply do not teach or suggest these claim limitations as recited in claims 23, 85, and 92. For the same reasons, Applicants submit that all claims depending from claims 23, 85, and 92 are not anticipated by Young et al.

Applicants respectfully request reconsideration and withdrawal of this rejection under 35 U.S.C. § 102(b).

Claim Rejections under 35 U.S.C. § 102(b)

Claims 23-24, 26-32, 37, 74, 85-96, 99-100 and 103-104 are rejected under 35 U.S.C. § 102(b) as being anticipated by Kohno et al. (Gene 188: 175-181, 1997; of record). Applicants respectfully traverse these rejections.

As an initial matter, Applicants note that the Examiner fails to provide any reasons why the novelty rejection (citing Kohno et al.) is maintained in view of Applicants' Response filed on August 21, 2006.

Applicants submit that the primer sequences and collar sequences of the claims are structurally tied to the "first portion" and the "second portion" of the polypeptide-encoding nucleic acid. Accordingly, the technical features that the first portion and the second portion of the polypeptide-encoding nucleic acid are a part of the claim limitations, which are necessary for construing the primer sequences and collar sequences of the claims.

Applicants reiterate the arguments already made of record that Kohno et al. simply do not teach or suggest the coding sequence of the mRNA encoding an antibody, the framework region associated with an antibody or the constant region associated with an antibody as recited in claims 23, 85, and 92. For the same reasons, Applicants submit that all claims depending from claims 23, 85, and 92 are not anticipated by Kohno et al.

Applicants respectfully request reconsideration and withdrawal of this rejection under 35 U.S.C. § 102(b).

**CONCLUSION**

For the foregoing reasons, Applicants respectfully request reconsideration and withdrawal of the pending rejections. Applicants believe that the claims are now in condition for allowance and early notification to this effect is earnestly solicited. Any questions arising from this submission may be directed to the undersigned at (617) 951-7000. If an additional fee is due, please charge our Deposit Account No. 18-1945, under Order No. ALEX-P01-055 from which the undersigned is authorized to draw.

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Respectfully submitted,

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